pharmaceuticals repackaged in unit dose formats. Under that guidance, many more products could be made available to the barcode unit dose packages.

It is currently interpreted to be only applied to the in-house repackaging dispensers, not to commercial repackagers. We encourage the FDA to consider the extension of that language to commercial repackagers. It would provide many more barcoded packages in hospitals today. Thank you.

MR. COUGHLIN: Hello. My name is Mike Coughlin. I'm the president and CEO of ScriptPro. ScriptPro develops and provides dispensing automation and robotics for pharmacies.

And unlike much of the discussion we've heard this afternoon, we work in the outpatient community/ambulatory pharmacy environment. And that's a very, very important environment. A very large number of prescriptions, the largest number, are filled there.

I wanted to show you how important barcode systems are in what we do. And I submitted a report to the docket here that you have. And I wanted you to be

able to see how these systems work, not just tell you how the systems work.

So you can go through and you can see how, in these kinds of environments, a drug product is picked up, a manufactured drug product. It is scanned, recognized by its barcode. It is poured into a robotic dispensing cell. That has a barcode on it. The robot manages the process by rechecking the cell. The robot prints a barcode label and puts it on the product. It puts a picture on the product.

The patient can take the product home, theoretically scan a barcode, see a picture of the drug they're taking, learn about it, see a picture of the drug on the label. It's all tied together. It's a complete link. That's sort of the heart of how these systems work. I've given you several examples in the reference material.

Obviously, these systems are barcode-driven. Barcodes are very important. Unfortunately, sometimes when the patient or the pharmacist scans that barcode with the NDC number on it, our famous NDC number doesn't produce the picture that they were expecting.

And this is a serious problem relating to data structure, organization, coordination, standards, et cetera.

That's the second half of the pictures in this report, which are not all that pleasant, because what what they're going to show you is that we have drugs out there that have the same barcode, but the drug appears four different ways. Okay?

We have drugs out there that are repackaged and relabeled, but the same barcode is there. We have drugs that are dispensed in different packages, and the same barcode may appear on one package and maybe not on another that's an interior pack.

It's very easy to find in our drug database systems -- it's very easy to find a barcode that maps back to multiple drug products. The numbering system for drugs has been used in different ways by different manufacturers and repackagers, sadly enough, and this is unfortunate. It's a data structure problem.

How did this happen? The National Drug Code neighbor, or NDC, administered by the FDA is a ten-digit number that's made up of three segments, the

manufacturer number, a number that identifies the product, a number that identifies the package size. But there is not even agreement, never has been, on the sizes of these three segments, or consistent use of these segments. And I've got examples here and pictures; you can see them.

For example, some manufacturers use the package size segment to indicate a medical property of the product. Maybe it works for their inventory control system, but that's not the way the NDC was supposed to be used.

There is so much confusion that most computer databases have expanded the NDC to eleven digits just to get drug numbers that are not duplicates. They do this by padding the FDA's NDC with a zero, sometimes at the front, sometimes at the middle, sometimes just before the end.

This has introduced even more confusion. You have before you graphic proof that in our country's drug numbering system, almost everything that can go wrong has gone wrong. Let's expand the use of the barcodes, but let's not do this on the foundation of

Murphy's law. Let's fix this foundation before we build it to the next level.

Besides dispensing errors, there are other serious problems facing pharmacy today: Critical shortage of pharmacists. Patient wait times are too long. Not enough time for patient counseling. The good news is that barcode-driven systems, properly designed, can help us solve all these problems at once.

I have a series of recommendations that are in the report: that we fix the numbering system itself; that we have a clear definition of what barcodes are on the drugs; and above all, get the lot numbers and expiration dates in these barcodes; and have a different barcode and a different drug number for a different drug, even if it only looks different, because if you can't verify it by looking at it, what good does the number do for you? Thank you very much.

MS. LONGE: My name is Karen Longe. My company is Karen Longe & Associates. And we specialize in assisting the healthcare industry in the use of automatic identification and data capture, including barcode. And I would like to thank the FDA and all of

you here for the opportunity to make comments on this issue that's really impacted the entire industry, right down from the manufacturer to the patients.

However, today I'm here as chair of the healthcare committee for AIM. AIM is the association of automatic identification data capture technologies. AIM is committed to standards development, education, and market promotion. It has a membership of over 900 companies, global companies, that provide the equipment and systems that capture, track, and transfer information about people, places, and things.

I would first of all like to compliment the healthcare industry for developing and approving standards. There are standards out there for making products. Those standards include the health industry barcode supplier labeling standard, the EAN/UCC system, and the ISBT-128 system we've heard about, as well as the health industry barcode provider application standard for identifying other things that we're probably not talking about today except for patients, that Ed Steane mentioned.

The most important part of developing the

standards was to identify the nature of the information that should be encoded in a barcode, and how the various elements of the information should be identified and presented. The really important part of that work, and perhaps really the one I noticed, was a realization that before considering a particular barcode symbology or any other kind of radio -- excuse me -- any kind of machine-readable technology, such as RFID or contact memory, the business problem had to be clearly defined.

This is because all of these technologies that can be used to automatically identify products and collect information, they're only tools. These technology tools continue to change and, fortunately, in most cases, improve.

I also would like to insert a word of caution. Some of the things we've been hearing today about the method to encode the information, to limit it to barcode only or, I think, even more dangerous is just specify only one barcode symbology.

Doing something like this would be like a specification back in the mid-'60s that said that all

information had to be collected on punch cards; or maybe the music industry said, okay, the only thing we're ever going to do is allow 33-1/3 LPs. Where would we be today? While I agree that standards are a must, please, don't be limited by the technical advancements. Don't limit it so the advancements -- you can't take advantage of them.

Another point that should be made: The industry is looking at barcoding as a tool to improve patient safety, but there are many other business benefits of barcoding that should not be overlooked. Manufacturers, distributors, healthcare facilities, will benefit from the ability to identify and track any type of product -- the drugs, medical devices, blood -- from the point of manufacturing through distribution to receiving, use by healthcare facility, and then of course the reordering process, and everything starts again.

The technology that works best on a pallet of products is not necessarily the one that works best at the unit dose or unit issued level: Again, my concern over legislating a technology rather than identifying

the elements of information and how they are presented. That's why healthcare developed standards that -- and they developed the standards that improved the standards that are based on data structures.

These standards allow for the use of several different AIM-approved and tested symbologies. Data structures provide a description and the order of the data to be encoded in a symbology or an RFI tag or a contact memory button.

Be assured, though, that current technology out there -- the barcode printers and scanners we've been talking about today -- they do produce and read the full range of publicly available barcode symbologies identified by the healthcare standards.

Mandating the use of appropriate machine-readable technology, using a health industry-developed and approved standard, will help to improve patient safety and improve efficiencies in the healthcare chain; will allow the industry to take advantage of advancements in technology to meet their own business needs. However, mandating a particular technology or a particular barcode symbology will limit the industry's

ability to reach its goals.

The members of AIM are ready to assist the FDA and the healthcare industry as it moves forward to gain the benefits offered by automatic identification and data capture. Thank you.

MS. SENSMEIER: My name is Joyce Sensmeier. I'm here on behalf of the Healthcare Information and Management Systems Society. It is a nonprofit association focused on advancing the best use of information and management systems for the betterment of human health.

We are based in Chicago. We have more than 13,000 individual members who work in healthcare organizations throughout the world. The individual members include healthcare professionals and hospitals, healthcare systems, clinical practice groups, healthcare information technology supply organizations, consulting firms, and government settings, in professional levels ranging from senior staff to CIOs. HIMSS also serves over 80 corporate members, which include suppliers and consultants in the health information and management systems industry.

HIMSS strongly supports industry cooperation in achieving viable point of care unit of use barcoding to reduce medical errors and improve productivity. HIMSS members represent all aspects of the supply chain impacted by unit of use barcode technology.

HIMSS is working to accelerate the adoption of barcoding at the point of care through several initiatives: publication of a white paper on barcoding; formation of a supply chain special interest group; formation of a barcoding task force; development of a flow chart describing the effect of barcoding technology on the continuum of care, which has been submitted to the docket as Exhibit A to my statement; joining the National Alliance for Health Information Technology as a founding member, and you heard from that group this morning.

We have plans for developing a barcoding handbook to assist providers with the implementation of this technology. And we have also developed a HIMSS position statement on point of care unit of use barcoding, which follows.

With the goal of moving towards a fully

electronic health record system, the Healthcare Information and Management System Society advocates the comprehensive use of standards-based barcoding technology in the healthcare environment.

And the Society recognizes that significant benefits of this technology can be brought forward in multiple areas, including: patient registration and admission; patient safety; clinical care delivery; patient tracking; product supply logistics; materiel management coordination; and patient accounting and billing, which was mentioned this afternoon, not altogether unimportant to some people.

At our annual conference in January, we polled attendees to see what was the use of barcoding technology in their organizations. Nearly 77 percent of the 619 respondents of the survey reported that their organization was using barcoding technology in some way.

The two areas which reported the most prevalent use were laboratory, 45 percent of the respondents, and the supply chain/materiels management at 40 percent. However, only 15 percent of our

respondents indicated that their organization used barcode technology for medication administration at the point of care.

It is our recommendation that barcoding be applied immediately to the medication administration process. Use of this technology, along with embedded decision support, which includes alerts and reminders, will go far to enhance patient safety at the point of care and provide the nurse with support in documenting and administering timely, accurate, and effective medication therapy.

On a personal note, I would like to share a brief experience that I witnessed back in the 1980s working as an R.N. in a 350-bed community hospital. I worked with a nurse named Claire who was exactly the kind of nurse that I would want taking care of me if I was a patient. She was bright, thorough, efficient. She questioned the physician's orders when they needed to be questioned. And she provided excellent care.

One day Claire made a grievous medication error. Her patient was a 300-pound truck driver who was recovering from arm surgery and various multiple

trauma injuries. He was on a blood thinner to prevent blood clots.

The dose was ordered for 9:00 a.m. daily, but we had a protocol in place that you should check the blood level of the drug prior to giving the medication. On this particular day, in a rush, Claire gave the blood thinner without checking the blood level. It so happened that the patient's blood level was high, and the patient bled internally into his surgical incision.

The blood was trapped. He developed compartmental syndrome, and eventually became disabled from his truck driving job. Needless to say, Claire was devastated by this situation, but each of us knew that it could have happened to any of us.

Today's environment in healthcare is even more challenging than in the 1980s: fewer resources, a nursing shortage, and patients in the hospital are sicker. Barcode technology provides a check and balance at the point of care. With embedded decision support, it could prevent errors like this. Please take action quickly so that this technology can be used to help us provide optimal patient care.

MR. ROSADO: Good afternoon. My name is Edith Rosado and I'm vice president of pharmacy affairs at the National Association of Chain Drug Stores.

NACDS is pleased to provide comments on the development of a regulation on barcode labeling for human drug products. NACDS supports the use of barcoding for all prescription products, vaccines, and over-the-counter medicines to help improve the quality of pharmacy care provided to patients, as well as to create efficiencies in the provision of prescription services.

NACDS membership includes more than 200 chain pharmacies that operate 33,000 community retail pharmacies. Chain pharmacy is the single largest segment of pharmacy practice, employing approximately 100,000 pharmacists.

Chain community pharmacy fills about 70 percent of the three billion prescriptions provided to patients each year. It is predicted that community pharmacy will fill roughly four billion prescriptions by the year 2004. And again, 70 percent of these prescriptions will be filled by chain community

pharmacy.

This fact, coupled with the continuing shortage of pharmacists, including 6500 vacancies alone just in chain community pharmacy, will require that community pharmacy seek technological solutions to keep up with the increasing demand of prescriptions in an efficient and a safe manner.

NACDS supports the use of barcode through that supports not only the NDC but also the lot number and expiration date of the product down to the unit of dispensing package. With all three pieces of information present, the product can then be tracked throughout the supply chain system from point of distribution from the manufacturer to the end user patient.

From a patient safety perspective, this is important information to have, especially during a drug recall. Additionally, having this information as part of the barcode makes tracking of inventory a much easier task. This becomes a useful tool when dealing with return goods and inventory management.

NACDS supports the use of barcodes as a way

to compliment the various programs that community pharmacies already have in place to enhance patient quality. Many automated dispensing systems that are in use today accomplish this goal.

A recent chain market survey shows that 45 percent of the chains surveyed use barcode scanning for data entry and prescription verification. One in particular allows the pharmacist to scan the barcode on the label of the completed prescription.

This allows viewing of the image of the correct product. The pharmacist can then compare and doublecheck the image against what is in the pharmacy container before it is ultimately dispensed to the patient.

Pilot tests are also being conducted to investigate the use of barcoding for proper drug selection. The barcode is scanned at the point of data entry so that the NDC, drug name, and strength automatically populates the necessary fields on the computer screen.

This eliminates the need to choose one drug from an entire alphabetic list. When all fields are

then populated, other dispensing functions, such as drug utilization review and billing, may also be conducted since many of these functions depend on the NDC number and specific product information.

Enhancing barcoding will substantially improve the current FDA recall system. In recall of product withdrawal situations, all affected product must be identified or removed from the marketplace. Especially during Class 1 recalls, the pharmacist must contact every person who has received the drug to warn them of possible adverse reactions as well as to communicate the need for product withdrawal.

If lot numbers were utilized as part of the barcode and recorded as part of the patient's prescription record, identification of the affected patient population then becomes easy. The pharmacist only needs to contact those patients that have actually received the affected product, eliminating unnecessary alarm to other patients since they would have to contact all patients that received the prescription in question.

Additionally, the pharmacist would also be

able to pull all this unwanted stock expeditiously from their pharmacy shelves, their warehouse, and distribution center.

Using barcodes could also facilitate other patient quality initiatives. New technologies exist that allow the physician to send the prescription electronically to the pharmacy provider of the patient's choice. Electronic prescribing helps to eliminate ambiguous abbreviations and specifies all elements needed for a complete order -- the drug name, dosage, directions, and the route of administration -- thereby reducing the chance for medication-related errors.

Barcoding technology also increases efficiency. In fact, barcoding technology could be considered as an alternative to keyboard data entry. Barcode scanners are faster than the human eye and much more accurate, and tests have shown that barcode information has an accuracy rate of one error in ten million characters, versus keyboard data entry error of one in 100.

Efficiencies and technology in community

retail pharmacy have allowed the pharmacist to spend less time on the administrative tasks of filling the prescription and more time interacting and counseling the patients about their prescriptions. A recent study conducted by Arthur Andersen found that pharmacists still perform many of the tasks filling prescriptions that do not really need to be performed by pharmacists.

That is, they're spending over two-thirds of their time on tasks such as computer data entry, counting and packaging medications, resolving prescription insurance program disputes, and other clerical activities. These non-clinical tasks consume pharmacists' valuable time that could be better devoted to patient care activities.

MS. DOTZEL: Thanks very much. We need to move on.

MR. RACK: I'm Robert Rack, president of Rack Design Group and BarcodeAmerica.com.

I have the benefit of 27 years of experience implementing automatic identification solutions in barcode, and maybe uniquely, six years experience working for a major pharmaceutical firm, so I

understand the issues from both sides, and providing end user solutions with our present company.

Let's not decide that a 1 percent implementation level dictates the technology chosen. The issues are safety, compatibility, reliability, affordability, product security. Commonality of data structures are a must. The ability to fit the data on the drug or medical device is paramount. Potential lethality of the drug or device should be considered in determining whether NDC number encoding alone is sufficient. Increased danger mandates NDC number, lot number, and expiry date and coding.

Product cost and potential for counterfeiting may mandate the use of a supplemental four-character alphanumeric serial number to identify it to the individual unit level. A four-character number would allow 1.6 million possibilities in a lot.

On some medical devices, this is necessary, too, to have traceability because you cannot tell by looking at the device if certain operational steps have been done on it, like heat treating and things of that nature.

In terms of choosing a symbology, we could use code 128. We could use RSS. We could use data matrix. All those codes should be acceptable. NASA did their evaluation of product marketing, and they chose data matrix codes, as have several other industries.

A point I'd like to make is that handheld readers capable of reading all existing codes can be purchased today for less than $500. By this time next year, due to the development of CMOS imagers on a chip, cost of handheld readers will drop to $200 to $250 to read every symbology that exists.

At this time, the capability for printing data matrix codes at the fastest line speeds exists. RSS can be printed at lower line speeds. High-speed thermal transfer or inkjet printing that can meet quality requirements in vision systems that can read and determine anti-print grades now exists for matrix codes, and can be run at line speeds up to 2,000 labels per minute.

We first installed data matrix systems on pharmaceutical lines in 1994. It's proven technology. Virtually any system installed in the pharmaceutical

industry over the last three years for human-readable date and lot inspection is also data matrix capable. The pharmaceutical manufacturer merely has to enable this capability.

High-speed machine vision systems capable of reading RSS will start becoming available within 60 days. These will initially command a premium price. Installed costs for such systems will start at about $16,000. Costs for installed medium-speed data matrix systems start at about $8,000. It is anticipated that at some future date, the same systems will read all the RSS variants at similar costs.

Data matrix could be installed and made operational sooner by pharmaceutical companies than RSS codes. It also uses the least label real estate, allowing it to fit where other symbologies will not.

Some existing online laser systems will be capable of being upgraded to RSS if the laser manufacturers have the incentive to do so. It's not assured.

What makes sense? Perhaps we should phase in lower lethality drugs first using only NDC or UCC/EAN

standards over the next 18 months. For higher lethality drugs or drugs with higher counterfeit potential, the NDC, lot and expiry, and possibly sequential numbers should be phased in over a 36-month period, giving time to acquire the printing systems, the online printing systems, that are needed and need to be implemented.

This way, the pharmaceutical manufacturers will have time to invest, install, and validate the online printing and inspection systems. People have to remember that time is required to do validation and do the equipment purchase. But the first phase will not require these upgrades to online printing capability since this data can be printed offline.

Manufacturers could also possibly chose the 50 percent of their products that will fall into the first phase. My concern otherwise is that implementation will be stalled and deadlines extended, much as what happened with component verification during the '90s.

Lastly, consider that image-based readers are capable of reading all symbologies and performing image

capture.

A point to consider: Perhaps if the physicians' signatures were captured, you would be more careful and lower the opportunity for transcription errors. Thank you.

MR. CREQUE: Good afternoon. I'm Stewart Creque, vice president of business development of findtheDOT. Thank you for allowing me to make this presentation to you today regarding the barcode labeling regulation. We put specific answers to your questions into our docket submission. I just want to use this presentation to set the background for that.

findtheDOT has developed a unique new technology for creating links between physical objects and digital data that relates to those objects. This alternative to barcode solves problems that have so far prevented wider acceptance of machine-readable codes for patient safety.

Automated identification of unit dose packages at the patient bedside is a key element and the last line of defense in preventing medication errors in the clinical setting. While bedside verification systems

using traditional barcodes have shown good success when used as designed in reducing medication errors, these systems have not achieved widespread acceptance. This is due to three factors.

The cost of packaging unit dose medications to fit barcodes: Traditional barcodes are large and therefore require large packages, which waste material and add cost. And they also rely on inline printing at production speeds for variable data elements.

Cost of bedside verification systems: Barcode scanners are relatively expensive and are incorporated into very costly systems requiring major IT investments. If the current barcodes are replaced by RSS, CS, or data matrix-type codes, acquisition costs of scanning hardware will rise substantially.

And third, reluctance of bedside staff to utilize unwieldy barcode scanning hardware and software: Barcode scanners are inconvenient at the bedside and the software driving them is generally complex, slowing down the bedside nurse.

findtheDOT's MedDot technology improves both sides of this tradeoff by offering, first, a code

physically small enough, just 5 millimeters in diameter, to fit onto existing packaging and on other small spaces such as infant wristbands or custom dispensing labels.

Second, low-cost readers within the reach of hospital capital budgets such that every bedside nurse can have a personal reader at an affordable total cost to the hospital, including a low-cost, low-power RF link in each device.

And third, a linking mechanism whereby any MedDot can link to a related data set that can contain any types and quantity of data, both static and dynamic. Dr. Combes of the AHA alluded to that in his remarks this morning.

This removes barriers both to rapid deployment of machine-readable codes on unit of use packages and rapid implementation of bedside scanning systems at hospitals. And further, because MedDots support a code space of ten billion billion unique values, each and every unit dose medication, biologic product, and medical device can have a unique serialized identifier link to a specific design, manufacturing, and use data,

including who ordered it, who dispensed it, and who administered it.

Instead of being forced to print at production line speeds, the manufacturer can preprint MedDots onto packaging material along with the nonvariable data, inspect them offline, and then pre-load the database with product information.

At the time of packaging, the manufacturer updates the MedDot database with the lot number and expiration date. And when the product is sold, the data can be transferred to a local system at the purchasing hospital. Of course, MedDots can also be generated in the hospital pharmacy for nonstandard or custom preparations.

On the nursing floor, a nurse uses the MedDot reader to identify the patients assigned to her that shift and each of her patients' medication orders, the MAR, are wirelessly transmitted to her MedDot reader. As she prepares to administer medication, she reads MedDots on the patient wristband and on the unit dose package and receives positive confirmation that the five rights of medication safety are satisfied, and, of

course, a negative confirmation if they are not.

MedDots all have the same small size and distinctive appearance for ease of visual identification. And the MedDot reading device can prompt for further data such as route of administration, and also can accept charting notes from a pocket menu card.

The system thus supports automated charting as well as reporting of near-misses or of errors. It also supports inventory control and other administrative functions in the hospital.

So this simple technology can be incorporated easily with existing hospital IT systems. And, moreover, findtheDOT will gladly license the MedDot reading capability to vendors of barcode-based systems, and we will also license pharmaceutical manufacturers and barcode equipment manufacturers at very low cost in order to make MedDots a healthcare standard. Since bedside scanning is still rare, there is really no significant installed base of barcode scanners to be displaced in that application.

The MedDot is an innovative technology that

breaks the existing logjam in acceptance of machine-readable codes for bedside verification, and as such, it offers an immediate increase in patient safety. Thank you.

MR. EDZENGA: Good afternoon to all that's left. I'm Larry Edzenga. I represent the vaccines biological products manufacturers' position on unit dose barcoding of VISI. Just a reminder:

VISI is the Vaccine Identification Standard Initiative. I'm representing the vaccine manufacturer member companies from Aventis Pasteur, Careon, GlaxoSmithKline, Merck, and Wyeth, working in conjunction with the Centers for Disease Control and Prevention, Bruce Weniger.

In our effort to reduce medical errors, the VISI members companies align with the PhRMA statement that was presented earlier as a co-contributor to the development of that document.

VISI members are -- I want to say, though, unlike PhRMA, our challenge with the vaccine and vaccine labeling is a little different than PhRMA's. It's included in PhRMA's recommendation. However, we

have some particular issues around size when it comes to prefilled syringes and vials.

So VISI member companies have researching barcode technologies in the market, done extensive work in this area, in our effort to meet very small available space to print on vaccine labels and at high running speeds in production, and in particular, variable data, and in particular, for the base label, let alone any detachable labels.

VISI member companies conclude that reduced size symbology is required, and specifically two-dimensional data matrix is selected code to barcode vaccine labels, again because of size. VISI member companies feel it has met the objective for vaccine standard barcode identification for users from affordable scanning technology now available, and can read multiple barcode symbologies.

VISI member companies, however, are also concerned the public health organizations and physician offices will use barcodes provided on labels by the industry. As we heard earlier, vaccines make up about 1 percent of hospital dispensing at bedside.

Government agencies will need to educate and poll the medical community for the appropriate use to meet the objectives barcodes are intended. VISI member companies want to continue to work with the CDC, the agency, and healthcare stakeholders of this process in an effort to reduce medical errors. Thank you.

MR. RIDDICK: I'm John Riddick, director of quality assurance and regulatory affairs for Novation. I requested to speak on behalf of Novation today because of my expertise in the regulatory and quality arena, especially as it relates to medical labeling and barcode applications. I also come to you today as a representative of America's leading hospitals.

Novation is the supply company of two large not-for-profit hospital alliances, VHA and UHC. These alliances represent more than 2,300 community-based medical centers ranging in size from 20-bed rural facilities to multi-thousand-bed teaching institutions. We estimate that the two alliances account for about 35 percent of the occupied beds in the country. In 2001, the purchases of Novation contracts amounted to almost $18 billion.

Through our work with Novation, we regularly come into contact with physicians, nurses, pharmacists, and other clinicians practicing in our hospitals of all sizes. Continually, they tell us that one of the top priorities for their hospitals, in keeping with their focus on patient safety and cost-effectiveness, is barcoding on as many medical products as possible. Selection of safer products and prevention of label mixups and medication errors are key goals in Novation institutions.

As part of our member-driven philosophy, Novation has launched a comprehensive safety initiative, including, among other programs, the requirement for machine-readable barcodes at unit of use. A daunting challenge for all of us is the application of barcodes on the very small product containers, especially pharmaceutical vials, in light of the FDA's current requirements around human readability.

There are certainly smaller barcodes in the newer emerging technologies. We all want to make sure that the systems in each of our individual hospitals

are capable of reading any applied barcoding.

As requested in the Federal Register, our guidance to FDA is as follows:

Number one, mandate the use of machine-readable barcodes at the unit of use level on all dosage forms of commercially available pharmaceutical products, blood products, and vaccines.

Number two, initially demand that all the information contained in the NDC number is included in that barcode.

Number three, with respect to time frames, urge the suppliers to make this change as soon as economically feasibly possible. Novation has set the deadline for our suppliers for 2004.

Number four, consider the inclusion of lot numbers and expiration dating in the barcode when the technology is more widely available and when the end users are more universally prepared to read and scan these new technologies within their institutions. Certainly, inclusion of the lot number and expiration date will benefit end users when tracking expired products or recalled products, and Novation supports

the inclusion and asks FDA to address it as soon as technically feasible.

Number five, eventually consider the use of barcodes on medical devices. As relates to safety issues, prevention of medication errors, et cetera, many medical devices would not even need a barcode. Priority should be given to those devices that have potential to adversely affect patient safety.

As stated by many here today, the critical need to move immediately in the area of pharmaceuticals should not be diluted by consideration of barcodes on medical devices at this time.

Number six, evaluate and promote new and emerging technologies that we've heard about so many times today, such as radio frequency, dot matrix, 2D, or NSS, as they become more readily available and easily embraced by end users.

In the near term, however, FDA should not require the application of barcodes beyond the scope of one-dimensional symbologies currently available and widely used.

And number seven, consider relaxing the rules

surrounding human-readability requirements, especially in the extremely small containers. If there were more space available on the small labels, the supplier and the end user would benefit from the added flexibility.

Although suppliers are in agreement that barcoding would be a positive step, all the ones that we talked to tell us the same thing we hear from our customers: Yes, it's something they would like to do. We feel that a standardized, comprehensive FDA directive will further move those suppliers to accept this important enhancement, as well as lead consistency to the process.

Most imply, these improvements could only promote patient safety and help to reduce medication errors while streamlining cost savings and efficiencies. Thank you.

MR. HENNUM: Hi. I'd like to thank the FDA for the opportunity to address the proposed regulation on barcode labeling. My name is Vaughan Hennum. I'm CIO for Portex, Inc., which is part of Smiths Medical. And I am representing an actual mid-sized device manufacturer selling to the acute care marketplace who

might be affected by a barcode regulation.

I'm going to focus principally on the economic impact questions, and try to share a few insights about what we think something like that might cost us. I think our situation might be illustrative for other suppliers. I think, honestly, just from a casual survey of other device manufacturers, device manufacturers have a way to go in this arena.

First off, will barcode printing costs cause changes in labeling for the Smiths medical companies, it absolutely will. We have implemented barcode item number case label printing, but we are not far along on unit of use.

There's no question that our regulatory function demands validation and verification of any barcode labels. That's a real cost. We do item numbers on the case label, but lot number and expiry dates, we've got a ways to go.

We do agree there are equipment solutions out there. But one of the things that really concerns us the most is the rate of technology acceptance and the time for this regulation to become effective.

I'm going to read you a quote. "HIDA and the industry need medical/surgical manufacturers to identify with industry standard product barcodes by" -- the target date for very small unit of use was July 1997. That was published in July 1995.

That hasn't happened, and the real question is, why not? And I think it comes down to, who is the owner or stakeholder of barcodes? If you examine other industries that have been very successful with barcoding throughout the supply chain, whether it's retail or automotive, ultimately you had a large end user who said, if you want to sell to me, you must barcode.

In Japan, which has been alluded to, we are actually seeing now some large university hospitals saying, even if the price is higher, we will buy only barcoded products at the unit of use level with lot number and with expiry date.

So the challenge, it seems to me, in the health industry, which does not have large consolidated hospitals to drive all elements of the supply chain to barcode, is how do we get there? The solution that

we're talking about is an FDA regulation, which has compliance through the entire supply chain.

The reality is, for a medical device manufacturer, barcoding at the unit of use level, item, lot number, expiry, will cost a significant amount of money and time to implement and to validate, with very little internal gain, especially considering, as someone pointed out today, the multiple language labels. And I'm going to actually go through what we've estimated our costs to be for our company.

So I guess I would say if we are to move forward with this expenditure to avoid the failures of past voluntary compliance initiatives, the regulation must cover the entire supply chain with standard, well-accepted barcode symbologies to avoid the high cost of new technology, with existing data structures such as UCC-128.

Just as a for instance, we have about 3,000 SKUs. We've estimated that to do the entire piece of capital investment as well as labor, IT, et cetera, would look like about $650,000. And that doesn't include the ongoing cost of additional labels.

For Smiths Medical, across all of the manufacturing companies, we've estimated that the cost would be three-quarters of a percent to 1 percent of our revenues to effect this regulation.

So in conclusion, then, my point in making this presentation is, we think the benefits appear to be clear for barcoding. It seems like it's a very good public policy to improve patient safety. But if the FDA regulates barcoding, it must drive that compliance throughout the entire medical device supply chain by regulation for patients to obtain the benefits of our expenditures.

I am not limited just to suppliers. We think that it would take us about two years to actually implement this regulation. We could do item number first. Lot number and expiry date are more challenging.

Thank you very much for the opportunity to make this presentation.

MR. PEOPLES: Okay. MACs people, are we still all awake? I am a pharmacist. I have both community and hospital experience. I currently am the president

of Rxscan. Rxscan has for several years developed national drug barcode scanning equipment and processes used to reduce medication dispensing and administration errors.

Currently, our equipment is used to verify the accurate dispensing of over 100 million prescriptions per year. Hopefully, this practical experience means I know something about what I'm going to talk about today.

Since we started out today with a video, as a windup, why don't we just do a quick 30-second live case demonstration. Here's the patient. This patient is represented by a barcode. I scan that barcode. The scanner now knows the information on what drug this patient is supposed to receive.

I now take my medication container. It could be this enteric coated aspirin that is barcoded here. I scan this product. It yells and screams at me and gives me a red light, saying I just about gave the wrong medication to this patient. That's two seconds, and it takes two seconds of training. This is what we've spent the whole day talking about. This is what

all of this effort is for.

Which medical products should carry a barcode? It is my belief that all healthcare products should carry a barcode. This includes medical supplies, prescription medical products, and over-the-counter should carry a national drug barcode.

It is necessary, obviously, to increase utilization of automation to decrease medication errors and distribution costs. We include nonprescription products because OTC medications are also administered to patients in healthcare facilities and sometimes dispensed by prescriptions in community pharmacies, OTC medicines, like aspirin, laxatives.

Everyone in here would like to make sure they receive the right laxative. Right? Or how about not get a laxative when they're not supposed to? Vitamins are often prescribed. Prescribing them is often done, so is there a complete medical record of what the patient is taking and the specific directions for that patient on that patient's container?

Currently many over-the-counter products, such as diabetic supplies and insulin, have both an NDC

number and a UPC, a universal product code number. And usually it is the universal product code number that is barcoded. Why did we have two identification numbers for the same product? Also, for billing purposes in healthcare, the UPC number is not normally recognized. It's only the NDC number.

Almost weekly, we hear of serious drug interactions occurring when mixing certain vitamins, herbals, and other OTC products with prescription medications. Having one ID number, the NDC number, barcoded on all over-the-counter products will expedite the identification of these potentially dangerous interactions using software drug interaction programs.

What information should be contained in the barcode? The minimum information is the National Drug Code. That is the common ID that we need to eliminate dispensing or administration errors. Lot number and expiration date? We've all got lots of great reasons why we need those, but it is not the most important element to eliminate these errors.

Our statistics show -- obviously, we can capture data in this scanner. Our statistics show that

over 5 percent of the first medication that is pulled from a shelf to supply to a patient is not the medication that is in the patient's medical record. Okay?

Should we adopt a specific barcode symbology? Pros and cons:

Pro: Adopting one barcode symbology would speed up the process of adopting universal medication barcode scanning by, A, allowing the hardware manufacturers producing everything from barcode readers to barcode printers to focus on making the best equipment at the best prices possible for a single symbology, not many different symbologies; B, the medication manufacturers and packagers to focus on getting barcoding accomplished as rapidly as possible.

Con: It restricts future adoption of improved barcode symbology technology.

We believe a compromise is to have just a general requirement that whatever we come out with has a linear component that will work with today's equipment. That way, today's stuff will continue to work for as long as it needs to work anywhere in the

distribution process.

What packages -- or where should it be on the package? We'd like to see it down to the package that gets closest to the patient. So here's a sample. There's a barcode on the outer package. It comes in boxes of three. This is an inner package. This is what the average person is going to get. It also has a barcode.

But what happens when we get into a situation where what the patient actually is going to get is the individual dose right here? Okay. That also is barcoded. That's what we mean when we say, get down to the dose that gets closest to the patient.

What products already contain barcodes?

MS. DOTZEL: I just need to ask you to wrap up.

MR. PEOPLES: Sure. Basically, in community pharmacy, which is where most of our stuff is used, most community pharmacy products are bulk. They're already packaged. The stuff that we're really talking about today is hospital and nursing home-based. Thank you very much.

MS. DOTZEL: Okay. Well, we heard a lot of great information this afternoon. I apologize to people for having to cut you short or not give you sufficient time to probably give us all the information that you wanted to give us.

Obviously, we, you know, heard a lot of really good things. We think that everybody out there has a lot of valuable information. And we encourage you to give us the additional information you have. Submit your comments to the docket.

As I said earlier today, the docket closes on August 9th. The docket number is on the notice, the meeting notice you have. And if you don't have a copy of that, you can probably still get a copy out of the registration desk or from our website.

I think we heard a lot of support today for this initiative. We heard a lot of people say that -- you know, express their feeling that we needed to approach this thoughtfully. We needed to think about, you know, the scope of this. We needed to think about implementing and how and how far we would go with our implementation.

And I think another big thing that we heard today was flexibility and the need to adopt something that does -- that allows for, you know, technological innovation as we move forward.

We appreciate everybody's input today. And again, I urge people to continue to give us that information over the course of the next few weeks while the docket is open. And with that, I will close the meeting. And thank you very much for your participation today.

(Whereupon, at 4:50 p.m., the public hearing was concluded.)

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